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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,098	01/14/2004	Alexander Kozak	800.1012DIV	3472
23280	7590	02/06/2006	EXAMINER	
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/757,098	Applicant(s) KOZAK ET AL.	
	Examiner Robert Shiao	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 12/14, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-17,19-26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10-17,19-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/856,009.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application: ISRAEL 127143 with a filing date 11/18/1998.
2. Amendment of claims 1, 11, 20, and 30, and cancellation of claims 8, 18, 27, and 33 in the amendment filed on December 14, 2005, is acknowledged. Claims 1-7, 9-17, 19-26, and 28-32 are pending in the application.

Responses to Election/Restriction

3. Applicant's election with traverse of Group I claims 1-26 (i.e., now are 1-7, 9-17, 19-26), in part, in the reply filed on December 14, 2005, is acknowledged. An elected species of compound of formula (I), wherein R1 is a saturated or unsaturated hydrocarbon chain having from 2 to 30 carbon atoms; R2 is a phospholipid head group selected from choline, ethanolamine, inositol and serine thereof; D is ibuprofen; Z is a saturated or unsaturated hydrocarbon chain having from 2 to 15 carbon atoms; and X is an amino group, is also acknowledged. The traversal is on the ground(s) that the instant restriction is narrow, i.e., the phospholipids head group of variable R2 are all presumed to a similar function. This is found persuasive, in part, and the reasons are given, *infra*.

Status of the Claims

4. Claims 1-7, 9-17, 19-26, and 28-32 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1-26 (i.e., now are 1-7, 9-17, 19-26), in part, drawn to compounds/ compositions of formula (I), wherein the variable D represents a carboxyl group, and said carboxyl group is selected from ibuprofen thereof; the variables R1, X and Z are as defined in claim 1; the variable R2 represents a phospholipids head group.

Moreover, each of Groups I-V is distinct and independent products, processes of making, or methods of use one from the other on the basis of structure defined in the claimed products as directed to various compounds of the formula (I) having various moiety containing a heteroary or heterocycle by variable D (i.e., pyrrolidiyl of ketorolac, thiazine of tenoxicam, pyridine of piroxicam) and they differ in elements, starting materials, reaction conditions, dose, administration, bonding arrangement and chemical property to such an extend that a reference anticipating compounds of any one group would not render another group obvious. Absent factual evidence to the contrary, each is a different invention.

The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually, i.e., the phospholipids head group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 1-7, 9-17, 19-26, in part, embraced in above elected subject matter, are

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prosecuted in the case. Claims 1-7, 9-17, 19-26, in part, not embraced in above elected subject matter, and claims 28-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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6. Claims 1-7, 9, 10-17, and 19-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 16 of Kozak et al. US 6,730,696. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim compounds/compositions of formula (I) and two compounds, i.e., 1-stearoyl-2-{3-[α -methyl-4-(2-methylpropyl)benzeneacetamido]propanoyl}-sn-glycero-3-phosphocholine, and 1-stearoyl-2-{3-[α -methyl-4-(2-methylpropyl)benzeneacetamido]hexanoyl}-sn-glycero-3-phosphocholine, as agents treating inflammation, see claims 1, claim 10, page 4, lines 19-22, and claim 20, page 7, lines 9-12. The instant compounds/compositions have been found on pages 5-58 of the specification.

Kozak et al. claim compounds/compositions of two compounds, i.e., 1-stearoyl-2-{3-[α -methyl-4-(2-methylpropyl)benzeneacetamido]propanoyl}-sn-glycero-3-phosphocholine, and 1-stearoyl-2-{3-[α -methyl-4-(2-methylpropyl)benzeneacetamido]hexanoyl}-sn-glycero-3-phosphocholine, as agents treating inflammation, see columns 35-37, i.e., claims 8 and 16.

The difference between instant claims and Kozak et al. is that instant claimed compounds/compositions are 1-stearoyl-2-{3-[α -methyl-4-(2-methylpropyl)benzeneacetamido]propanoyl}-sn-glycero-3-phosphocholine, and 1-stearoyl-2-{3-[α -methyl-4-(2-methylpropyl)benzeneacetamido]hexanoyl}-sn-glycero-3-phosphocholine of claim, while Kozak et al. claims 17 compounds/compositions including instant compounds/compositions. It is noted that the variable D of instant compound of formula

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(I) represents ibuprofen, which is Kozak et al. α -methyl-4-(2-methylpropyl)benzeneace moiety of the same compounds.

One having ordinary skill in the art would find the claims 1-7, 9-17, and 19-26 prima facie obvious because one would be motivated to employ the compounds/compositions of Kozak et al. as agents treating inflammation to obtain instant claimed compounds/compositions of formula (I), wherein the variable R1 is a saturated or unsaturated hydrocarbon chain having from 2 to 30 carbon atoms; R2 is a phospholipid head group selected from choline, ethanolamine, inositol and serine thereof; D is ibuprofen; Z is a saturated or unsaturated hydrocarbon chain having from 2 to 15 carbon atoms; and X is an amino group, i.e., compounds of formula (I) are 1-stearoyl-2-{3-[α -methyl-4-(2-methylpropyl) benzeneacetamido] propanoyl}-sn-glycero-3-phosphocholine, and 1-stearoyl-2-{3-[α -methyl-4-(2-methylpropyl) benzeneacetamido] hexanoyl}-sn-glycero-3-phosphocholine, and their compositions, i.e., see instant claims 1, 10 and 20.

The motivation to make the claimed compositions derives from the expectation that the instant claimed compounds/compositions derived from known Kozak et al. compounds/compositions would possess similar activities (i.e., agents treating inflammation) to that which is claimed in the reference.

Objection

7. Claims 25-26 are drawn to a pharmaceutical composition and intent of use treating disease or disorder related to an inflammatory condition. However, the instant

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claims do not limit named diseases of intent of use, i.e., disease or disorder related to an inflammatory condition, or neurological diseases and disorders, which is objected by the Examiner. Incorporation of named diseases into the claim, would obviate the objection, also see page 9, lines 1-10 of the specification.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626



Joseph K. McKane
Supervisory Patent Examiner
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January 18, 2006